

REMARKS

The application includes claims 2 and 4-27.

Claims 2 and 4-27 were rejected as being anticipated by newly cited U.S. Patent Application Publication No. 2001/0051882 to Murphy. This rejection is traversed for many of the same reasons the previous rejections based on the Herren, Brown and Linder references were overcome.

In particular, Murphy does not disclose or suggest

- providing a clinical trial module to a client when the client elects to participate in the trial, where the clinical trial module permits clinical trial data including data observations for the trial to be obtained from the client;
- receiving data observations at the server and storing them; or
- producing reports based on a plurality of observations which are obtained during the conduct of the clinical trial.

In view of this, claims 2 and 4-27 are not anticipated by Murphy, and would not be obvious over any combination of the references of record.

Claim 2 requires, in addition to matching a user to a clinical trial based on the users profile:

providing to said client a selected clinical trial module, indicated by said clinical trial selection and corresponding to a selected one of said matching clinical trials, said module being adapted to obtain clinical trial data including a respective data observation;

receiving, at said server, said respective data observation;

storing said respective data observation in a database of data observations;

and

in response to a report request;

retrieving selected ones of said data observations from said database in accordance with parameters in said report request to provide a plurality of observations; and

producing a report based on said plurality of retrieved observations.

Claim 14 requires that the clinical trail data server, in addition to having a data engine for receiving a user profile and a clinical trials management module for matching a client to one or more clinical trials, has

one or more clinical trial modules adapted to obtain clinical trial data, including respective data observations.

Claim 26 requires that the clinical trial client, in addition to having a module for sending user profile to a clinical trial data server and being able to receive matching information from the clinical trial data server, has

a module for accepting a user selection of one of said one or matching clinical trials, and sending to said clinical trial data server a clinical trial solution;
and

a module for receiving and installing a selected clinical trial module corresponding to said clinical trial selection, the selected clinical trial module being adapted to obtain clinical trial data, including a respective data observation, from a clinical trial subject.

Murphy wholly lacks the underlined features noted in the independent claims above. Murphy describes a “matching system” which might best be described as a sophisticated search engine for a clinical trials database. The end result of Murphy management system and process is either a list of matched clinical trials or no results/matches. As explained in the Abstract of Murphy, the “clinical trials for which the user qualifies is then presented to the user”. With reference to Figures 1 and 2 of Murphy, it can be seen that the “Match System 110” is the central feature of Murphy. Figure 3 shows a “new trial match notification 375” and Figure 6 shows a display of match results.

The claimed invention allows for running a clinical trial within the application framework. While potential matches of clinical trials and users are made based on user data, the claimed invention provides that once the trial has been identified, the user selects it and once s/he has been accepted for participation, the system access or downloads the trial module or an application component specifically designed to run seamlessly within the framework, and the trial module, after installation, allows for collecting trial data from the clinical trial participant (including device and manually input data). Figure 7 of the application shows sending the clinical trials management module to the client, or indicating to the client that s/he has not been approved. Figure 8 of the application shows clinical data being collected from the client and being processed (see step 1420). Figure 11 shows data collection, and Figure 12 show data graphing within the

context of the claimed invention.

That is, the invention provides a system and method where a user can learn about clinical trials, apply for inclusion in the clinical trials, be accepted to or declined for inclusion in the clinical trials, and when accepted, be provided with module specific to the clinical trial which allows data to be collected from the individual and be usable within the context of a clinical trial (i.e., the data must include all of the information required for that particular trial in a format according to the requirements of the trial itself).

The Examiner has erroneously concluded that Murphy shows providing a client with a clinical trial module 320. As explained in paragraph 24 of Murphy, 320 (shown in Figure 3), is an “initial assessment”, which is a questionnaire “that will immediately narrow the list of trials for which the user may be a potential candidate” (see sentence bridging pages 2 and 3). Thus, Murphy is not showing providing a module for a particular trial from a server to a client; rather, 320 is part of the matching analysis and performs no function whatsoever in gathering clinical trial specific data.

The Examiner has erroneously concluded that Murphy shows a module for obtaining clinical data including a respective data observation. With reference to paragraph 24 of Murphy, it can be seen that no clinical data and no “respective data observation” of any kind is being provided in Murphy. Rather, paragraph 24 explains that a matching procedure is employed which has essentially a filtering step where, through answers to a questionnaire, the number of potential trials in which the user might participate is narrowed. Murphy provides no indication of acceptance into a clinical trial and provides no way of obtaining data observations relevant to any particular clinical trial.

The Examiner has erroneously concluded that Murphy shows receiving respective data observations at the server. With reference to paragraph 34 of Murphy, it is explained that the system “allows the users of the integrated care management system easy access to clinical trial information provided by the matching system. It also provides a pool of individuals against which the criteria for specific trials can be compared, to identify possible candidates.” (Emphasis added). As noted above, paragraph 34 is concerned with matching people to trials, and it has no indication whatsoever that data observations relevant to a particular

trial can be collected. As emphasized by underlining possible candidates, it should be clear from paragraph 34 of Murphy that no particular candidate has been enrolled in a trial and no relevant observations from the candidate are being collected.

Similar to the above, the Examiner has incorrectly concluded that respective data observations are stored in a database and that reports which includes a plurality of retrieved observations are created. As explained in detail above, paragraphs 24 and 34 are related solely to matching and identification procedures whereby a possible candidate for a trial can be identified. Murphy does not sent show or suggest a method or system where a clinical trial module is sent to a client after, and after acceptance in a trial, observations from the client are sent to the server.

The Examiner has erred in concluding that Figure 3 of Murphy shows a medical device which can provide observations for use in a clinical trial. Figure 3 of Murphy only shows a system which employs a clinical trial matching process whereby potential candidates for a clinical trial can be identified. Figure 3 of Murphy does not show collection of any relevant observations for use in a clinical trial.

The Examiner has erroneously concluded that Murphy shows health data management module comprises data analysis algorithms used by said data engine to analyze said clinical trial data. As noted above, paragraphs 24 and 34 pertain to a matching system, but do not describe or suggest a clinical trial module being provided to a client, or use of the clinical trial module to obtain relevant observations that are usable in a clinical trial.

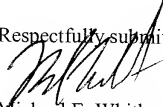
In view of the foregoing, it is respectfully requested that the application be reconsidered, that claims 2 and 4-27 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephonic or personal interview.

A provisional petition is hereby made for any extension of time necessary for the continued pendency during the life of this application. Please charge any

fees for such provisional petition and any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



Michael E. Whitham
Reg. No. 32,635

Whitham, Curtis & Christofferson, P.C.
11491 Sunset Hills Road, Suite 340
Reston, VA 20190

Tel. (703) 787-9400
Fax. (703) 787-7557

Customer No.: 30743